IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

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| IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION | ) | MDL NO. 1203 |
| THIS DOCUMENT RELATES TO: | ) | |
| SHEILA BROWN, et al. | ) | |
| v. | ) | CIVIL ACTION NO. 99-20593 |
| AMERICAN HOME PRODUCTS CORPORATION | ) | 2:16 MD 1203 |

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8954**

Bartle, J. November 7, 2012

Margaret A. Wood ("Ms. Wood" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust").[2] Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[3]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Michael T. Wood, Ms. Wood's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In August, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Roger W. Evans, M.D., F.A.C.P., F.A.C.C. Dr. Evans is no stranger to this litigation. According to the Trust, he has signed in excess of 318 Green Forms on behalf of claimants seeking Matrix Benefits. Based on an echocardiogram dated January 21, 2002, Dr. Evans attested in Part II of Ms. Wood's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to

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3. (...continued)
contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

60%.[4] Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $501,985.[5]

In the report of claimant's echocardiogram, the reviewing cardiologist, David J. Kardesch, M.D., F.A.C.C., stated under the heading "IMPRESSION" that "[t]here was trivial mitral regurgitation" and under the heading "Mitral Valve" that there was moderate regurgitation. Dr. Kardesch, however, did not specify a percentage as to claimant's level of mitral regurgitation.[6] Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

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4. Dr. Evans also attested that claimant suffered from mild aortic regurgitation. This condition is not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's findings of an abnormal left atrial dimension or a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

6. Claimant also submitted an echocardiogram report prepared by Dr. Evans in May, 2002 based on her January 21, 2002 echocardiogram. In this report Dr. Evans stated that "[t]he mitral valve shows moderate mitral regurgitation. The RJA/LAA ratio is 25%."

In June, 2005 the Trust forwarded the claim for review by Donna M. Polk, M.D., M.P.H., one of its auditing cardiologists. In audit, Dr. Polk concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. In support of this conclusion, Dr. Polk explained that "[t]he mitral regurgitation is just above the cutoff for physiologic exceeding 1 cm in several views thereby making it mild. It is not however greater than 20% of the left atrial area size. There are no volumetric measurements done in the echo."[7]

Based on Dr. Polk's finding that claimant had mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. Wood's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.[8] In contest, claimant submitted an affidavit from Dr. Evans, who confirmed his previous finding and stated that "the echocardiogram tape shows 'moderate' mitral

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7. Physiologic regurgitation is defined as a "[n]on-sustained jet immediately (within 1 cm) behind the annular plane or <5% RJA/LAA." See Report of Auditing Cardiologist Opinions Concerning Green Form Questions at Issue, at 2.

8. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Wood's claim.

valve regurgitation with a RJA/LAA ratio of approximately 25%. This is seen in the apical 4-chamber views." Claimant argued, therefore, that she had established a reasonable medical basis for her claim. Claimant further asserted that the auditing cardiologist "apparently did not understand the difference between his personal opinion ... and the 'reasonable medical basis' standard." (Emphasis in original.)

The Trust then issued a final post-audit determination, again denying Ms. Wood's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Wood's claim should be paid. On November 3, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 5833 (Nov. 3, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on January 10, 2006, and claimant submitted a sur-reply on March 9, 2006. Under the Audit Rules it is within the Special Master's discretion to appoint a Technical Advisor[9] to review claims after the Trust and claimant

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9. A "[Technical] [A]dvisor's role is to act as a sounding board (continued...)

have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Sandra V. Abramson, M.D. F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding that she had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

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9. (...continued)
for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

In support of her claim, Ms. Wood repeats the arguments she made in contest; namely, that the affidavit of Dr. Evans provides a reasonable medical basis for the claim. Claimant also contends that the concept of inter-reader variability accounts for the difference between the opinion provided by Dr. Evans and that of the auditing cardiologist, Dr. Polk. According to claimant, there is an "absolute" inter-reader variability of 15% when evaluating mitral regurgitation. Thus, according to Ms. Wood, if the Trust's auditing cardiologist or a Technical Advisor concluded that the RJA/LAA ratio for a claimant is 5%, a finding of a 20% RJA/LAA ratio by an attesting physician is medically reasonable.

In response, the Trust argues that the affidavit of the attesting physician does not establish a reasonable medical basis for Ms. Wood's claim because Dr. Evans merely restates his previous findings and does not refute the auditing cardiologist's specific conclusions. The Trust also notes that Dr. Evans does not address the original echocardiogram report prepared by Dr. Kardesch, which indicates that claimant had only "trivial" mitral regurgitation. The Trust further asserts that inter-reader variability does not account for the difference in findings of the attesting physician and the auditing cardiologist because Dr. Polk specifically found that there was no reasonable medical basis for the representation of moderate mitral regurgitation made by Dr. Evans.

The Technical Advisor, Dr. Abramson, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. Specifically, Dr. Abramson found that:

> In reviewing the transthoracic echocardiogram, my visual estimate is that there is only mild mitral regurgitation. I measured the mitral regurgitant jet and the left atrial area (in the same frame) in five representative cardiac cycles. My measurements for mitral regurgitant jet area/left atrial area are $1.2cm^2/12.8cm^2$, $1.1cm^2/13.8cm^2$, $1.0cm^2/15.8cm^2$, $1.2cm^2/15.8cm^2$ and $1.0cm^2/14.2cm^2$. These ratios are 9%, 8%, 6%, 8% and 7%, all of which are considerably less than 20%, and consistent with mild mitral regurgitation. There are no measurements on the tape for me to critique.

Dr. Abramson further stated that "it would be impossible for a reasonable echocardiographer to interpret this severity of mitral regurgitation as moderate."

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, claimant does not refute the specific conclusions of the auditing cardiologist or the Technical Advisor. Claimant does not rebut the auditing cardiologist's determination that "[t]he mitral regurgitation is just above the cutoff for physiologic exceeding 1 cm in several views thereby making it mild."[10] Nor does she challenge the Technical Advisor's conclusion that claimant's RJA/LAA ratios

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10. For this reason as well, we reject claimant's argument that the auditing cardiologist simply substituted her opinion for the diagnosis of the attesting physician.

were "9%, 8%, 6%, 8% and 7%, all of which are considerably less than 20%, and consistent with mild mitral regurgitation."[11] Neither claimant nor her attesting physician identified any particular error with the findings of the auditing cardiologist and the Technical Advisor. Mere disagreement with the auditing cardiologist or the Technical Advisor without identifying any specific errors by them is insufficient to meet a claimant's burden of proof.

Moreover, claimant's reliance on inter-reader variability to establish a reasonable medical basis for the attesting physician's representation that Ms. Wood had moderate mitral regurgitation is also misplaced. The concept of inter-reader variability is already encompassed in the reasonable medical basis standard applicable to claims under the Settlement Agreement. In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's RJA/LAA ratios were all less than 10% and the auditing cardiologist determined that claimant's RJA/LAA ratio was never above 20%. Adopting claimant's argument that inter-reader variability expands the range of moderate mitral regurgitation by ±15% would allow a claimant with an RJA/LAA ratio as low as 5% to recover Matrix Benefits. This result would render meaningless this critical provision of the Settlement Agreement.

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11. Despite an opportunity to do so, claimant did not submit a response to the Technical Advisor Report. See Audit Rule 34.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of Ms. Wood's claim for Matrix Benefits and the related derivative claim submitted by her spouse.